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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/821,498	03/29/2001	Eileen C. Fuchs	112701-200	5214

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EXAMINER	
PRATT, HELEN F	

ART UNIT	PAPER NUMBER
1761	

DATE MAILED: 01/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/821,498	FUCHS ET AL.	
	Examiner	Art Unit	
	Helen F. Pratt	1761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 January 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other. .

DETAILED ACTION

Claims 1-36 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a ratio of fatty acids omega 6 to omega 3, does not reasonably provide enablement for a ratio of omega 3 to omega 6 of 5:1 to about 10:1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. Applicant cites page 2, line 31- to p. 3 line 1 for support. However, the specification also discloses on page 8, support for the ratio of omega 6 to omega 3. It is not seen how both of these ratios are correct. Clarification is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-4, 9-12, 15-19, 22, 23, 26-30, 33, 34 are rejected under 35 U.S.C. 102(a) as being anticipated by Mark et al. (6,200,950).

The claims are rejected for the reasons of record.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4, 6-12, 15-23, 26-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mark et al. in view of Whitney et al.

The claims are rejected for the reasons of record cited in the last office action.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mark et al. in view of Whitney et al. as applied to claims 1-4, 6-12, 15-23, 26-34 above, and further in view of Ballevre et al. Kawasaki et al. an Etzel.

The claim is rejected for reasons cited in the last office action.

Claims 13, 14, 24, 25, 35, 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mark et al. in view of Whitney as applied to claims 1-4, 6-12, 15-23, 26-34 above, and further in view of Cavaliere et al. The claims are rejected for the reasons of record cited in the last office action.

ARGUMENTS

Applicant's arguments filed 1-7-04 have been fully considered but they are not persuasive. Applicants argue that the reference to *Mark* is to a seriously ill person, but that the claimed methods are to improved muscles protein synthesis and that Mark does not mention the word "muscle", or preventing muscle loss or accelerating muscle recovery and that a different class of people is addressed such as the elderly, convalescent and anorexic patients. However, the phrase "for improving muscle protein synthesis" is seen as an intended use as in claim 1 and similarly in the other independent claims. Claim 1 only says that it is a method for improving muscle protein synthesis by administering an effective amount of the composition. The composition has been shown as known. Applicants do not argue that it is not. The reference

discloses that the amount of protein in the composition is optimal for moderate tissue repair of the targeted population (col. 3, lines 35-45). The claimed ingredients have been shown in the claimed amounts, so protein synthesis must have been improved using the claimed composition. Also, as in the Mark et al. in view of Whitney rejection, Whitney et al. disclose that it is known that muscles are made of protein and that particular amounts of protein are designed to cover the need to replace protein containing tissue which is lost (page 178, col. 2, 2nd complete para. and pages 138 and 139). Even in a 102 rejection, Whitney can be used as a teaching reference. As to the different class of people addressed, no class is seen in claim 1. In claim 15 "individuals at risk" are part of the intended use. Certainly seriously ill people are such, and this would cover anorexic people and illness in the elderly.

Applicants argue as to the 103 rejection and particularly that Whitney is to building muscles in athletes, using diet and exercise regimes. However, Whitney was used to show that muscles are made of protein as cited before.

Applicants argue that the further reliance on the remaining references is not proper. However, the references were used for what they teach and the whole invention does not need to be found in one reference. Ballevre et al. disclose that a protein composition containing can be used in a nutritional supplement, and Kawasaki et al. that it is known to use GMP's in food, and Etzel that is it known to use GMP in nutraceuticals. Further reasons for the use of these references are cited in the last art rejection.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helen F. Pratt whose telephone number is 571-272-0404. The examiner can normally be reached on Monday to Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Milton Cano, can be reached on (571) 272-1398. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-0987.

Hp 1-14-04

HELEN PRATT
PRIMARY EXAMINER